

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH CAROLINA  
BEAUFORT DIVISION**

The United States of America and the States	)	
of North Carolina, California, Colorado,	)	
Delaware, Florida, Georgia, Illinois, Indiana,	)	
Iowa, Louisiana, Michigan, Minnesota, New	)	
Jersey, New York, Tennessee, Texas, Virginia	)	
and Wisconsin, <i>ex rel.</i> Scarlett Lutz, Kayla	)	
Webster, Dr. Michael Mayes and Chris	)	
Reidel,	)	
	)	<b>CA No.: 9:14-cv-00230-RMG</b>
Plaintiffs,	)	(Consolidated with 9:11-cv-1593-RMG
	)	and 9:15-cv-2485-RMG)
vs.	)	
	)	
Berkeley Heartlab, Inc., Bluewave Healthcare	)	
Consultants, Inc., Latonya Mallory, Floyd	)	
Calhoun Dent, III and Robert Bradford	)	
Johnson,	)	
	)	
Defendants.	)	

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**UNITED STATES' AMENDED PROPOSED JURY INSTRUCTIONS**

Pursuant to Local Civil Rule 26.09, the United States respectfully submits the attached twenty-eight jury instructions, tailored for the trial in this case. Other than a single proposed instruction summarizing the allegations in this case, each of the instructions consists of a separate legal principle, without undue repetition, relating to the False Claims Act, 31 U.S.C. §§ 3729–33, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, medical necessity, invocation of the Fifth Amendment by defendants’ co-conspirators, the defendants’ asserted advice of counsel defense, or damages.

As compared to the United States’ prior filing of proposed jury instructions on October 25, 2017 (Dkt. Nos. 700 and 705), the United States’ proposed jury instructions filed today (Dkt. No. 755) include changes to five proposed jury instructions. In particular, Instructions 2.3 and

6.1 were revised to account for the Court’s ruling that it “will not provide” an instruction using the term “tainted.” (Dkt. No. 715 at 4.) The support for Instruction 2.15 was supplemented to include a recently-decided case. Instruction 3.1 was modified to correct a typographical error. Lastly, Instruction 5.1 was revised to account for the Court’s rulings regarding the BlueWave Defendants’ asserted advice of counsel defense. (Dkt. No. 693 at 16-17; *id.* at 18.)

The United States does not seek to modify the Court’s preliminary and boilerplate jury instructions set forth in Judge Gergel’s Special Instructions that are applicable in this case. The United States may seek to supplement, modify, or withdraw these proposed instructions before or during trial.

Respectfully submitted,

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## **1. The Case**

### **1.1. Summary of Allegations [United States]**

The United States alleges that the BlueWave Defendants knowingly caused Health Diagnostics Laboratories, Inc. (HDL) and Singulex, Inc. to submit claims to Medicare and TRICARE for medically unnecessary services and for services resulting from violations of the Anti-Kickback Statute.

The United States alleges that Mallory knowingly submitted, and caused HDL to submit, claims to Medicare and TRICARE for medically unnecessary services and for services resulting from violations of the Anti-Kickback Statute.

The United States alleges that defendants knowingly made, used, and caused to be made or used, false records and statements material to false or fraudulent claims.

The United States alleges that defendants conspired to violate the False Claims Act.

Sources: U.S. Compl., Dkt. No. 75; Order on Mots. to Dismiss, Dkt. No. 268 at 8–16.

## 2. False Claims Act

### 2.1. False Claims Act Liability [United States]

The False Claims Act is a federal law designed to discourage fraud against the federal government. The False Claims Act authorizes the United States Government to recover damages caused by false or fraudulent claims for money or property of the United States.

In this case, there are three ways in which a defendant may be found liable for violating the False Claims Act.

First, a defendant may be found liable for knowingly submitting or causing the submission of a false or fraudulent claim to the United States.

Second, a defendant may be found liable for knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.

Third, a defendant may be found liable for conspiring with one or more other persons to submit or cause the submission of a false or fraudulent claim.

Sources: 31 U.S.C. § 3729(a)(1)(A)–(C); Order on Mots. to Dismiss, Dkt. No. 268 at 8–16; Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 11 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 27 (E.D. Va. Aug. 1, 2014); Jury Instructions, *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Dkt. No. 434 at 5–6 (S.D. Tex. Nov. 18, 2016).

## 2.2. Burden of Proof [United States]

To prove a violation of the False Claims Act, the United States must prove each of the elements by a preponderance of the evidence.

Sources: 31 U.S.C. § 3731(d) (“In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.”); Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 11 (D.S.C. May 8, 2013); Jury Instructions, *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Dkt. No. 434 at 6 (S.D. Tex. Nov. 18, 2016); *ACLU v. Holder*, 673 F.3d 245, 249 (4th Cir. 2011); *United States v. Rogan*, 459 F. Supp. 2d 692, 716 & n.12 (N.D. Ill. 2006) (preponderance of evidence standard applies to all essential elements of FCA claim, including AKS predicate), *aff’d*, 517 F.3d 449 (7th Cir. 2008); *see also Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 491 (1985) (“In a number of settings, conduct that can be punished as criminal only upon proof beyond a reasonable doubt will support civil sanctions under a preponderance standard.” (collecting cases)); *S. Atl. P’ship of Tenn., L.P. v. Riese*, 284 F.3d 518, 530 (4th Cir. 2002) (civil RICO predicates must be proven by preponderance of evidence).



## 2.2. Claim Defined [United States]

As used in the False Claims Act, a “claim” is any request or demand for money where the United States Government provides any portion of the money requested. In this case, the claims are the requests for reimbursement submitted by HDL and Singulex to Medicare and TRICARE for laboratory testing services. It does not matter if the request for reimbursement was submitted in paper or electronic form.

Sources: 31 U.S.C. § 3729(b)(2); *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968) (“claim” under the False Claims Act refers to “all fraudulent attempts to cause the Government to pay out sums of money”); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015) (“[E]ach time [defendant] submitted to Medicare a UB–92/04 form asking for reimbursement for a prohibited referral, it was knowingly asking the government to pay an amount that, by law, it could not pay. Consequently, we find the district court did not err in finding that each UB–92/04 form constituted a separate claim.”).

### 2.3. False or Fraudulent Claim [United States]

A claim, statement, or record is “false or fraudulent” if it is untrue when submitted, made, or used. A claim, statement, or record is also “false or fraudulent” if a defendant makes representations in submitting a claim, but fails to disclose material violations of statutory, regulatory, or contractual requirements, and that failure to disclose makes the defendant’s representations about those services misleading. In other words, misleading half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be “false or fraudulent claims.”

Any claim that includes an item or service resulting from a violation of the Anti-Kickback Statute is a false or fraudulent claim. Any claim that includes an item or service that is medically unnecessary is a false or fraudulent claim.

Sources: 31 U.S.C. § 3729(a)(1)(A)–(B); Order on Summ. J. Mots., Dkt. No. 693 at 14 (“[A] claim tainted by the AKS is a false or fraudulent claim for FCA purposes.”); Order on Mots. to Dismiss, Dkt. No. 268 at 8 (“Any claim tainted by an AKS violation constitutes a false or fraudulent claim.”); *United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016) (“By punishing defendants who submit ‘false or fraudulent claims,’ the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions.”); *id.* (“[T]he term ‘fraudulent’ is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud.”); *United States ex rel. Lutz v. BlueWave Healthcare Consultants, Inc.*, 853 F.3d 131 (4th Cir. 2017) (“An AKS violation that results in a federal health care payment is a per se false claim under the FCA.”); *Harrison v. Westinghouse Savannah R. Co.*, 176 F.3d 776, 787 (4th Cir. 1999) (“The phrase ‘false or fraudulent claim’ in the False Claims Act should be construed broadly. The False Claims Act is ‘intended to reach all types of fraud, without qualification, that might result in financial loss to the Government . . . [T]he Court has consistently refused to accept a rigid, restrictive reading. . . .’” (citing *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968))); *United States v. Mensah*, 737 F.3d 789, 804 (1st Cir. 2013) (approving instruction in criminal case that “[a] statement is false if it was untrue when made”), *cert. denied*, 134 S. Ct. 1912 (2014); *United States v. Rogan*, 517 F.3d 449, 452–53 (7th Cir. 2008) (holding that all claims submitted by defendant were false because they resulted from kickbacks); *United States ex rel. Local 342 Plumbers & Steamfitters v. Dan Caputo Co.*, 321 F.3d

926, 933 (9th Cir. 2003); *see also United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015) (holding defendant was “knowingly asking the government to pay an amount that, by law, it could not pay” each time it submitted a claim tainted by a Stark Law violation); Jury Instructions, *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Dkt. No. 434 at 7 (S.D. Tex. Nov. 18, 2016).

## 2.4. Causation [United States]

In order to find that a defendant's conduct caused false claims to be submitted, or caused false records or statements to be made or used, you must determine that the conduct was a substantial factor in producing the harm and that the outcome was foreseeable. You may find that causation was established even if you find that HDL and Singulex, the laboratories who submitted the claims to the United States, did not know that the claims, records, or statements were false. It is not necessary for a defendant to receive the money directly from the Government; causing the payment of Government money to some individual or entity will suffice.

Sources: 31 U.S.C. § 3729(a)(1)(A)–(B); Order on Mots. to Dismiss, Dkt. No. 268 at 10 (“Taking the allegations as true and applying the traditional tort principles of proximate causation, the Court finds that HDL’s and Singulex’s submission of false claims was the necessary, foreseeable, and obvious consequence of these Defendants’ participation in the abovementioned schemes.” (citing *United States ex rel. DeCesare v. Americare in Home Nursing*, 757 F. Supp. 2d 573, 589 (E.D. Va. 2010))); Order at 14 (“[T]he creation of false records (e.g., false Medicare forms) is the necessary, foreseeable, and obvious consequence of Defendants’ improper inducements such as providing kickbacks or promoting medically unnecessary testing.”); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 37 (E.D. Va. Aug. 1, 2014); *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544–45 (1943) (“[FCA] reach[es] any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government.”); *United States ex rel. Watson v. King-Vassel*, 728 F.3d 707, 714–15 (7th Cir. 2013) (applying in FCA case “traditional, time-tested notions of [proximate] causation” as “that which, in a natural and continuous sequence, unbroken by any efficient intervening cause, produces the injury and without which the result would not have occurred”); *United States ex rel. Riley v. St. Luke’s Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004) (“The FCA applies to anyone who knowingly assists in causing the government to pay claims grounded in fraud, without regard to whether that person has direct contractual relations with the government.” (quotation marks omitted)).

## **2.5. Knowledge [United States]**

For purposes of the False Claims Act, the terms “knowing” and “knowingly” mean that a defendant, with respect to information:

- (1) had actual knowledge of the information; or
- (2) acted in deliberate ignorance of the truth or falsity of the information; or
- (3) acted in reckless disregard of the truth or falsity of the information.

The United States does not need to prove that any defendant specifically intended to defraud the government.

Source: 31 U.S.C. § 3729(b)(1); Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 11–12 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 38 (E.D. Va. Aug. 1, 2014); Jury Instructions, *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Dkt. No. 434 at 6 (S.D. Tex. Nov. 18, 2016).

## 2.6. Actual Knowledge [United States]

“Actual knowledge” means affirmative knowledge that the claims, or records or statements, were false.

The United States may establish that a defendant had actual knowledge through circumstantial evidence. For example, if it appears that a certain condition existed for a substantial period of time, and that defendant had regular opportunities to observe the condition, then you may draw the inference that the defendant had knowledge of the condition.

Sources: 31 U.S.C. § 3729(b)(1)(A)(i); Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 12 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 39 (E.D. Va. Aug. 1, 2014); *United States ex rel. Stone v. Rockwell Int’l Corp.*, 282 F.3d 787, 811–812 (10th Cir. 2002) (approving instruction that in considering whether defendant knowingly made any false statements, jury “must consider all direct and circumstantial evidence”); *Jones v. Otis Elevator Co.*, 861 F.2d 655, 661 n.11, 665 (11th Cir. 1988) (approving instruction that “Knowledge or notice may also be established by circumstantial evidence. If it appears that a certain condition has existed for a substantial period of time and that the defendant had regular opportunities to observe the condition, then you may draw the inference that he had knowledge of the condition”).

## 2.7. Deliberate Ignorance [United States]

“Knowledge” under the False Claims Act also includes acting in deliberate ignorance of the truth or falsity of the information.

The United States can prove “deliberate ignorance” through proof that a defendant deliberately closed its eyes to clear warning signs or to what otherwise would have been obvious to it. A finding that a defendant purposely avoided learning all the facts, or suspected a fact but refused to confirm it, also constitutes deliberate ignorance. Stated another way, a defendant’s knowledge of a fact may be inferred from willful blindness to the existence of the fact.

Sources: 31 U.S.C. § 3729(b)(1)(A)(ii); Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-cv-02858-MBS, Dkt. No. 810 at 12 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 41 (E.D. Va. Aug. 1, 2014); S. Rep. No. 99-345, at \*7, 21 (1986); *United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001-02 (2016) (“[B]ecause a reasonable person would realize the imperative of a functioning firearm [when the Government orders guns], a defendant’s failure to appreciate the materiality of that condition would amount to ‘deliberate ignorance’ or ‘reckless disregard’ of the ‘truth or falsity of the information’ even if the Government did not spell this out.”); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 382 (4th Cir. 2015) (“warnings” and “subsequent inaction” are probative of knowledge); *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001) (“Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment.”); *Mackby*, 261 F.3d at 828 (“[Defendant’s] claim that he did not know of the Medicare requirements does not shield him from liability. By failing to inform himself of those requirements, particularly when twenty percent of [his clinic’s] patients were Medicare beneficiaries, he acted in reckless disregard or in deliberate ignorance of those requirements, either of which was sufficient to charge him with knowledge of the falsity of the claims in question.”); *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 154 (D. Mass 2008) (“[H]aving entered into the rebate agreements, the defendants were required, as a matter of law, to familiarize themselves with the legal requirements, standards and procedures of the Medicaid program,” including “the procedures and legal requirements applicable to reimbursements”); *United States ex rel. Ervin & Assocs., Inc. v. Hamilton Secs. Grp., Inc.*, 370 F. Supp. 2d 18, 41–42 (D.D.C. 2005) (defendant must make “such inquiry as would be reasonable and prudent to conduct under the circumstances to ascertain the true and accurate basis of the claim”).

## 2.8. Reckless Disregard [United States]

“Knowledge” under the False Claims Act also includes acting in “reckless disregard” of a claim’s truth or falsity.

The United States can prove “reckless disregard” through proof that a defendant was reckless in determining whether a claim was true or false. An innocent mistake or mere negligence is not sufficient to constitute knowledge under the False Claims Act. But if a defendant failed to make such inquiry as would be reasonable and prudent, that is evidence of “reckless disregard.”

Sources: 31 U.S.C. § 3729(b)(1)(A)(iii); Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-cv-02858-MBS, Dkt. No. 810 at 12 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 40 (E.D. Va. Aug. 1, 2014); *United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001–02 (2016) (“[B]ecause a reasonable person would realize the imperative of a functioning firearm [when the Government orders guns], a defendant’s failure to appreciate the materiality of that condition would amount to ‘deliberate ignorance’ or ‘reckless disregard’ of the ‘truth or falsity of the information’ even if the Government did not spell this out.”); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 380 (4th Cir. 2015) (“The purpose of the FCA’s scienter requirement is to avoid punishing ‘honest mistakes or incorrect claims submitted through mere negligence.’”) (quoting *United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010)); *United States ex rel. Watson v. King-Vassel*, 728 F.3d 707, 713 (7th Cir. 2013) (“[FCA plaintiff] need only show that [defendant] had reason to know of facts that would lead a reasonable person to realize that [defendant] was causing the submission of a false claim . . . or that [defendant] failed to make a reasonable and prudent inquiry into that possibility . . . .”); *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001) (“Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment.”); *Mackby*, 261 F.3d at 828 (“[Defendant’s] claim that he did not know of the Medicare requirements does not shield him from liability. By failing to inform himself of those requirements, particularly when twenty percent of [his clinic’s] patients were Medicare beneficiaries, he acted in reckless disregard or in deliberate ignorance of those requirements, either of which was sufficient to charge him with knowledge of the falsity of the claims in question.”); *United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997) (“[FCA] defines reckless disregard as an extension of gross negligence.”).



## 2.9. Materiality [United States]

Under the False Claims Act, the term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

A matter is material if a reasonable person would attach importance to it in determining his or her choice of action; or if the defendant knew or had reason to know that the Government attaches importance to the matter.

Whether laboratory services resulted from violations of the Anti-Kickback Statute is material. Likewise, whether laboratory services were medically unnecessary is material.

Sources: 31 U.S.C. § 3729(b)(4); 42 U.S.C. § 1320a-7b(g); Order on Mots. to Dismiss, Dkt. No. 268 at 13 (“Any documentation (that is, any record or statement) that must be submitted to Medicare or TRICARE for reimbursement is material because it has a natural tendency to influence, or be capable of influencing, the Government’s decision to pay.” (quotation marks omitted)); *United States ex rel. Lutz v. BlueWave Healthcare Consultants, Inc.*, 853 F.3d 131 (4th Cir. 2017) (“An AKS violation that results in a federal health care payment is a per se false claim under the FCA.”); *United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002–03 (2016) (explaining, by reference to the common law, that a matter is material: “(1) if a reasonable man would attach importance to it in determining his choice of action in the transaction; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action, even though a reasonable person would not” (quotation marks and alterations omitted)); *Escobar*, 136 S. Ct. at 2003 (“[A]n undisclosed fact was material because [n]o one can say with reason that the plaintiff would have signed this contract if informed of the likelihood of the undisclosed fact.” (quotation marks omitted)); *Escobar*, 136 S. Ct. at 2003 (noting violation of collusive bidding requirement was material because “the government’s money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive” (quoting *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943))); *Neder v. United States*, 527 U.S. 1, 16 (1999) (“In general, a false statement is material if it has a natural tendency to influence, or is capable of influencing, the decision of the decision-making body to which it was addressed.” (quotation marks omitted)); *United States v. Triple Canopy, Inc.*, 857 F.3d 174, 179 (4th Cir. 2017) (“Guns that do not shoot are as material to the Government’s decision to pay as guards that cannot shoot straight.”); *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 914, 916–17 (4th Cir. 2003) (“Courts give effect

to the FCA by holding a party liable if the false statement it makes . . . has a natural tendency to influence or is capable of influencing the government's funding decision, not whether it actually influenced the government not to pay a particular claim.").

## 2.10. Elements of Conspiracy [United States]

In order for a defendant to be liable for a conspiracy to violate the False Claims Act, the United States must prove by a preponderance of the evidence that:

- (1) a conspiracy existed to submit or cause the submission of a false or fraudulent claim;
- (2) the defendant knowingly and willfully joined and participated in the conspiracy; and
- (3) at least one overt act in furtherance of the conspiracy was knowingly and willfully committed by at least one member of the conspiracy.

Source: 31 U.S.C. § 3729(a)(1)(C) (as revised by Pub. L. No. 111–21 § 4 (May 20, 2009), to abrogate *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662 (2008)); Order on Mots. to Dismiss, Dkt. No. 268 at 14–16; Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 31–32 (E.D. Va. Aug. 1, 2014); *United States v. Miller v. Bill Harbert Int’l Constr., Inc.*, 608 F.3d 871, 899 (D.C. Cir. 2010) (applying “the elements of common law civil conspiracy”), *cert. denied*, 563 U.S. 987 (2011); *United States ex rel. Durcholz v. FKW, Inc.*, 189 F.3d 542, 545 n.3 (7th Cir. 1999) (noting that “general civil conspiracy principles apply” to FCA conspiracy claims (citing *United States v. Murphy*, 937 F.2d 1032, 1039 (6th Cir. 1991))); *United States v. Rogan*, 459 F. Supp. 2d 692, 718–19, 726 (N.D. Ill. 2006) (“General civil conspiracy principles apply to FCA claims . . . . To prevail, the Government need only show a single illegal plan, a shared general conspiratorial objective, and an overt act committed in furtherance of the conspiracy that damaged the United States.”), *aff’d*, 517 F.3d 449 (7th Cir. 2008); *United States ex rel. DeCesare v. Americare in Home Nursing*, 757 F. Supp. 2d 573, 586, 590–91 (E.D. Va. 2010).

## 2.11. Definition of Conspiracy [United States]

A “conspiracy” is an agreement among two or more persons to achieve an unlawful object, in this case, to submit or cause the submission of a false or fraudulent claim.

To show a conspiratorial agreement, the United States is not required to prove that two or more people entered into a solemn pact, but only that two or more persons explicitly or implicitly came to an understanding to achieve the specified unlawful object, whether or not they were successful. Also, it is not necessary for the United States to prove that the conspiracy lasted throughout the entire period that pertained to the object of their conspiracy, but only that it existed for some time within that period.

The existence of a conspiracy may be established by circumstantial evidence. You may conclude that a defendant joined a conspiracy even in the absence of evidence directly showing an express or formal agreement. Rather, you may infer that an agreement existed between defendants, or between a defendant and other conspirators, from any collection of circumstances tending to show a mutual understanding, spoken or otherwise, that the members would cause to have a fraudulent claim paid by the United States.

Source: 31 U.S.C. § 3729(a)(1)(C); Order on Mots. to Dismiss, Dkt. No. 268 at 14–16; Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 31–32 (E.D. Va. Aug. 1, 2014); *Walters v. McMahon*, 795 F. Supp. 2d 350, 358 (D. Md. 2011), *aff’d*, 684 F.3d 435 (4th Cir. 2012), *cert. denied*, 568 U.S. 1212 (2013); *Buschi v. Kirven*, 775 F.2d 1240, 1251 (4th Cir. 1985); *Greenville Publ’g Co. v. Daily Reflector, Inc.*, 496 F.2d 391, 399 (4th Cir. 1974); *United States v. Murphy*, 937 F.2d 1032, 1039 (6th Cir. 1991); *United States v. Rogan*, 459 F. Supp. 2d 692, 718–19 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008); *United States ex rel. Durcholz v. FKW, Inc.*, 189 F.3d 542, 546 (7th Cir. 1999) (“[Plaintiff] is not required to show an express agreement; conspiracies, by their very nature, are not often susceptible to direct proof.”).

## 2.12. Joining Conspiracy [United States]

A defendant joins a conspiracy if he or she agrees with a conspirator to participate in the project or enterprise that is the object of a scheme involving others and knowingly acts in furtherance of that object.

It is not necessary, however, that a defendant know all the details of the conspiracy, or all of its participants. He or she may not know more than one other member of the conspiracy, or more than one of its objects. He or she may have joined the conspiracy at any time in its duration, and may not have received any benefit in return. However, mere association with a conspirator does not make a defendant a member of the conspiracy even if he or she knows of the conspiracy. In other words, knowledge is not enough; the defendant must intentionally participate in the conspiracy with the purpose of helping to achieve at least one of its unlawful objects.

Source: 31 U.S.C. § 3729(a)(1)(C); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 31–32 (E.D. Va. Aug. 1, 2014); *United States v. Cornell*, 780 F.3d 616, 630–31 (4th Cir. 2015); *United States v. Sosa*, 777 F.3d 1279, 1291–92 (11th Cir. 2015); *United States v. Rogan*, 459 F. Supp. 2d 692, 719 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008).

### 2.13. Overt Act [United States]

An “overt act” is any act knowingly committed by at least one member of the conspiracy, not necessarily a defendant, in an effort to accomplish some object or purpose of the conspiracy.

The overt act need not be unlawful, if considered separately and apart from the conspiracy. It must, however, be an act which tends toward accomplishment of the plan or scheme and must be knowingly done and in furtherance of some object or purpose of the conspiracy.

Source: 31 U.S.C. § 3729(a)(1)(C); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 31–32 (E.D. Va. Aug. 1, 2014); *United States v. Cardwell*, 433 F.3d 378, 391 (4th Cir. 2005) (“[E]ach co-conspirator need not take an overt act in order to be convicted of conspiracy so long as one conspirator does so.”), *cert. denied*, 547 U.S. 1061 (2006); *United States v. Rogan*, 459 F. Supp. 2d 692, 718–19 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008).

## 2.14. Co-Conspirators' Acts and Statements [United States]

The Court has admitted into evidence against defendants the acts and statements of others, because these acts and statements were committed by persons alleged to be confederates or co-conspirators of the defendants.

If you find that a defendant was a member of the conspiracy, then any act or statement by any member of the conspiracy made in furtherance of the conspiracy may be considered against the defendant. This is so even if the acts were done and the statements were made in the defendant's absence and without the defendant's knowledge. On the other hand, if the acts were done or the statements were made by someone whom you did not find was a member of the conspiracy, or if they were not done or said in furtherance of the conspiracy, they may be considered by you only as evidence against the person who said or did them.

Source: 31 U.S.C. § 3729(a)(1)(C); Fed. R. Evid. 801(d)(2)(E); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 31–32 (E.D. Va. Aug. 1, 2014); *Bourjaily v. United States*, 483 U.S. 171, 176 (1987); *United States v. Ayala*, 601 F.3d 256, 267–68 (4th Cir. 2010), *cert. denied*, 562 U.S. 910 (2010); *United States v. Squillacote*, 221 F.3d 542, 563–64 (4th Cir. 2000), *cert. denied*, 532 U.S. 971 (2001); *United States v. Rogan*, 459 F. Supp. 2d 692, 718 n.13 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008).

## 2.15. Liability of Co-Conspirator [United States]

If liability for conspiracy under the False Claims Act is established, each conspirator is liable for each of the overt acts committed pursuant to the conspiracy and for the damages arising from the conspiracy even if he or she did not personally commit all of the acts that may take place under the conspiracy.

Source: 31 U.S.C. § 3729(a)(1)(C); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 31–32 (E.D. Va. Aug. 1, 2014); *Smith v. United States*, 568 U.S. 106, 111 (2013) (“Since conspiracy is a continuing offense, a defendant who has joined a conspiracy continues to violate the law through every moment of the conspiracy’s existence, and he becomes responsible for the acts of his co-conspirators in pursuit of their common plot.” (citing *United States v. Kissel*, 218 U.S. 601, 610 (1910), and *Hyde v. United States*, 225 U.S. 347, 369 (1912) (quotation marks and alterations omitted)); *United States v. Cardwell*, 433 F.3d 378, 391 (4th Cir. 2005), *cert. denied*, 547 U.S. 1061 (2006); *United States v. Gibson*, 2017 WL 5150282, at \*6 (5th Cir. Nov. 7, 2017) (“[A] juror could rationally convict the [defendants] on the substantive AKS counts” because defendants are “responsible for foreseeable kickbacks paid while the [defendants] were members of the kickback conspiracy”) (citing *Pinkerton v. United States*, 328 U.S. 640, 645–48 (1946)); *United States v. Rogan*, 459 F. Supp. 2d 692, 718–19 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008).



## 2.16. Invocation of Fifth Amendment [United States]

You have heard testimony in which certain witnesses invoked the Fifth Amendment to refuse to answer one or more questions. A witness has a constitutional right to refuse to answer a question on the ground that it may tend to incriminate him or her. However, you may consider a witness' refusal to answer a question as evidence in this case.

In addition, you may make certain inferences from a witness' refusal to answer a question. You may, but are not required to, infer by such refusal that the answer would have been unfavorable to the witness' interest. And, if you find that such witness was a member of a conspiracy to violate the False Claims Act, you may, but are not required to, infer by such refusal that the witness' answer would have been unfavorable to the interest of any co-conspirator.

Any inferences you may draw should be based on all of the facts and circumstances in this case as you may find them.

Source: *Flame S.A. v. Freight Bulk Pte. Ltd.*, 807 F.3d 572, 590 (4th Cir. 2015) (“[I]n the context of the Fifth Amendment’s privilege against self-incrimination, . . . a court may draw ‘adverse inferences against parties to civil actions when they refuse to testify in response to probative evidence offered against them.’” (quoting *Baxter v. Palmigiano*, 425 U.S. 308, 318, (1976))); *ePlus Tech., Inc. v. Aboud*, 313 F.3d 166, 179, 183–84 (4th Cir. 2002); *Coquina Investments v. TD Bank, N.A.*, 760 F.3d 1300, 1311–12 (11th Cir. 2014) (concluding, where evidence suggested witness “knew of and participated in” the alleged fraud, “we have no difficulty concluding that the adverse inferences drawn against [defendant] based upon [witness’] invocation of the Fifth Amendment privilege” were trustworthy); *LiButti v. United States*, 107 F.3d 110, 123–24 (2d Cir. 1997); *Brink’s Inc. v. City of New York*, 717 F.2d 700, 707–10 (2d Cir. 1983) (approving instruction where defendant’s former employees asserted Fifth Amendment privilege at trial); *RAD Servs., Inc. v. Aetna Cas. & Sur. Co.*, 808 F.2d 271, 275 (3d Cir. 1986); *Rosebud Sioux Tribe v. A&P Steel, Inc.*, 733 F.2d 509, 522–23 (8th Cir. 1984); *United States ex rel. DRC, Inc. v. Custer Battles, LLC*, 415 F. Supp. 2d 628, 633 (E.D. Va. 2006); Jury Instructions, *McClintick v. Leavitt*, No. 05-cv-2880, Dkt. No. 81 at 16 (D. Md. June 26, 2008).

### **3. Anti-Kickback Statute**

#### **3.1. Solicitation or Receipt [United States]**

In this case, there are two ways in which a defendant may be found to violate the Anti-Kickback Statute. First, a defendant violates the Anti-Kickback Statute if you find by a preponderance of the evidence that:

- (1) the defendant asked for or received any remuneration (including any kickback, bribe, or rebate) directly or indirectly, openly or secretly, in cash or in kind;
- (2) the payment asked for or received was in return for arranging for or recommending purchasing or ordering any item or service that could be paid for, in whole or in part, by Medicare or TRICARE; and
- (3) the defendant did so knowingly and willfully.

Sources: 42 U.S.C. § 1320a-7b(b)(1)(A)–(B); Eric Wm. Ruschky, Pattern Jury Instrs. For Fed. Crim. Cases, D.S.C. at 580 (Aug. 15, 2016 Online Ed.).

### **3.2. Offer or Payment [United States]**

A second way a defendant violates the Anti-Kickback Statute is if you find by a preponderance of the evidence that:

- (1) the defendant offered or paid any remuneration (including any kickback, bribe, or rebate) directly or indirectly, openly or secretly, in cash or in kind;
- (2) the offer or payment was made to a person to induce that person to do one of the following:
  - a. to refer an individual to a person for the furnishing or arranging for the furnishing of an item or service that could be paid for, in whole or in part, by Medicare or TRICARE; or
  - b. to purchase, order, or arrange for or recommend purchasing or ordering any item or service that could be paid for, in whole or in part, by Medicare or TRICARE; and
- (3) the defendant did so knowingly and willfully.

Sources: 42 U.S.C. § 1320a-7b(b)(2)(A)–(B); Eric Wm. Ruschky, Pattern Jury Instrs. For Fed. Crim. Cases, D.S.C. at 580 (Aug. 15, 2016 Online Ed.).

### 3.3. Purpose [United States]

The United States must prove that at least one purpose of the remuneration was the referral of individuals, such as patients, or the ordering of services, such as laboratory services, which may be paid for in whole or in part by Medicare or TRICARE.

It is not a defense that there might have been other reasons for the remuneration, if you find by a preponderance of evidence that at least one of the purposes for the remuneration was the referral of individuals or ordering of services to be paid for by Medicare or TRICARE.

Sources: 42 U.S.C. § 1320a-7b(b)(1)–(2); Order on Mots. to Dismiss, Dkt. No. 268 at 10 n.3 (“[T]he appropriate test for whether the waiver of a copay constitutes remuneration is whether the complaint has alleged that at least one of the purposes of the waiver was to induce patient referrals.”); *United States v. Borrasi*, 639 F.3d 774, 780–82 (7th Cir. 2011) (“We join our sister circuits in holding that if part of the payment compensated past referrals or induced future referrals, that portion of the payment violates [the AKS]”); *United States v. Greber*, 760 F.2d 68, 71–72 (3d Cir. 1985) (holding that AKS is violated if “one purpose of the payment was to induce future referrals,” “even if the payments were also intended to compensate for professional services.”), *cert. denied*, 474 U.S. 988 (1985); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (following *Greber*); *United States v. McClatchy*, 217 F.3d 823, 835 (10th Cir. 2000) (“[A] person who offers or pays remuneration to another person violates the Act so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals.”), *cert. denied*, 531 U.S. 1015 (2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); Eric Wm. Ruschky, Pattern Jury Instrs. For Fed. Crim. Cases, D.S.C. at 581 (Aug. 15, 2016 Online Ed.) (“The government must prove that a purpose of the remuneration was to induce the referring of patients or ordering of services.” (citing *Greber*)).

### 3.4. Remuneration [United States]

“Remuneration” under the Anti-Kickback Statute includes any payment or other benefit, including the waiver of a financial obligation, as long as at least one purpose of the payment or benefit was to induce referrals, even if the payment or benefit was also intended to compensate for professional services.

Thus, remuneration includes not only sums for which no actual service was performed but also those amounts for which some professional time was expended.

Sources: 42 U.S.C. § 1320a-7b(b)(1)–(2); Order on Mots. to Dismiss, Dkt. No. 268 at 10 n.3 (“[T]he appropriate test for whether the waiver of a copay constitutes remuneration is whether the complaint has alleged that at least one of the purposes of the waiver was to induce patient referrals.”); *United States v. Greber*, 760 F.2d 68, 71–72 (3d Cir. 1985) (holding that AKS is violated if “one purpose of the payment was to induce future referrals,” “even if the payments were also intended to compensate for professional services.”); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (following *Greber*); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 29–31 (1st Cir. 1989) (“Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.”); *United States v. Hancock*, 604 F.2d 999, 1001–02 (7th Cir. 1979) (finding indictments “adequately allege[d] the crime of receiving kickbacks” in the form of “handling fees” despite defendants’ arguments that such fees were for the “services of obtaining, packaging, and sending the samples”) (applying 1972 version of Medicare AKS); *United States v. Borrasi*, 639 F.3d 774, 780–82 (7th Cir. 2011); *United States v. McClatchy*, 217 F.3d 823, 835 (10th Cir. 2000), *cert. denied*, 531 U.S. 1015 (2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 68 (D. Mass. 2011) (“Congress’s intent in placing the term ‘remuneration’ in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.” (quoting 56 Fed. Reg. 35,952, 35,958 (July 29, 1991))); Eric Wm. Ruschky, Pattern Jury Instrs. For Fed. Crim. Cases, D.S.C. at 582 (Aug. 15, 2016 Online Ed.) (citing *Greber*); HHS-OIG, *Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B*, 59 Fed. Reg. 65,372, 65,374–75 (Dec. 19, 1994) (“When providers, practitioners or suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them.”).

### **3.5. Knowingly [United States]**

Under the Anti-Kickback Statute, knowingly means the act was done voluntarily and intentionally, not because of mistake or accident.

Sources: 42 U.S.C. § 1320a-7b(b)(1)–(2); *id.* § 1320a-7b(h); Order on Mots. to Dismiss, Dkt. No. 268 at 8; *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); Eric Wm. Ruschky, Pattern Jury Instrs. For Fed. Crim. Cases, D.S.C. at 582–83 (Aug. 15, 2016 Online Ed.) (citing *Davis*).

### 3.6. Willfully [United States]

Under the Anti-Kickback Statute, an act is done willfully if it is done voluntarily and purposely and with the bad purpose either to disobey or disregard the law. In order to act willfully, a defendant must act unjustifiably and wrongly while knowing that his or her actions are unjustifiable and wrong. A defendant need not be aware of the specific law or rule that his or her conduct may be violating.

Sources: 42 U.S.C. § 1320a-7b(b)(1)–(2); *id.* § 1320a-7b(h) (“With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”); Pub. L. 96-499 § 917 (1980) (adding phrase “knowingly and willfully” to AKS); H.R. Rep. No. 1167, 96th Cong., 2d Sess. 59 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5572 (explaining that “knowingly and willfully” were added to AKS to avoid penalizing individuals “whose conduct, while improper, was inadvertent”); Order on Mots. to Dismiss, Dkt. No. 268 at 9 (“To prove a violation of the AKS, the Government will need to show that Defendants acted with a purpose to commit a wrongful act.” (citing *United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000), *cert. denied*, 531 U.S. 1015 (2000)); *United States v. Sosa*, 777 F.3d 1279, 1293 (11th Cir. 2015); *United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013); *United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013) (“[AKS] Section 1320a–7b(h) clarifies that the Government is not required to prove actual knowledge of the [AKS] or specific intent to violate it. . . . As applied to [defendant], the Government was only required to prove that [defendant] willfully solicited or received money for referring Medicare patients to [payor of kickbacks]”); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Starks*, 157 F.3d 833, 837–38 (11th Cir. 1998); Eric Wm. Ruschky, Pattern Jury Instrs. for Fed. Crim. Cases, D.S.C. at 583 (Aug. 15, 2016 Online Ed.).

#### **4. Medical Necessity**

##### **4.1. Reasonable and Necessary [United States]**

Medicare and TRICARE reimburse only for items or services that are medically necessary. Medically necessary means that the items or services must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part.

All diagnostic laboratory tests must be ordered by a physician or nonphysician practitioner who consulted with or treated a patient for a specific medical problem and who used the test results in the management of the patient's specific medical problem. Tests otherwise ordered are not medically necessary.

Sources: 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1); 32 C.F.R. § 199.4(a)(1)(i); 42 C.F.R. § 410.32(a); Order Denying Mot. to Exclude Dr. Trost, Dkt. No. 585 at 2 n.1 (“Under 42 U.S.C. § 1395y(a)(1)(A), Medicare only reimburses services that are medically necessary for the diagnosis or treatment of an illness or injury.”).



## 5. Affirmative Defense(s)

### 5.1. Good Faith Reliance on Advice of Counsel [United States]

Each defendant has asserted an affirmative defense of good faith reliance on the advice of counsel. You may consider the advice given by counsel to a defendant in deciding whether the defendant acted knowingly and willfully if you find that, before taking action, the defendant:

- (1) in good faith sought the advice of an attorney whom the defendant considered competent for the purpose of securing advice on the lawfulness of the defendant's possible future conduct;
- (2) made a full and accurate report to the attorney of all material facts which the defendant knew;
- (3) reasonably relied on the attorney's advice; and
- (4) acted strictly in accordance with the advice of the attorney who had been given a full report.

The mere fact of consulting an attorney is insufficient. In determining whether a defendant reasonably relied on the advice of its counsel, you may consider all the advice given to a defendant by any source.

Sources: Order on Summ. J. Mots., Dkt. No. 693 at 16–17 (“To prevail on an advice of counsel defense, the Blue Wave Defendants must establish by a preponderance of the evidence that they: (1) sought the advice in good faith; (2) provided full and accurate information to their attorneys; (3) reasonably relied on the advice; and (4) faithfully followed that advice.”); *United States v. Joshua*, 648 F.3d 547, 554 (7th Cir. 2011); *see also Williamson v. United States*, 207 U.S. 425, 453 (1908) (“[N]o man can willfully and knowingly violate the law and excuse himself from the consequences thereof by pleading that he followed the advice of counsel.”); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 381 (4th Cir. 2015) (“[I]n determining whether [defendant] reasonably relied on the advice of its counsel, the jury was entitled to consider *all* the advice given to [defendant] by *any* source.” (emphasis in original)); *Tuomey*, 792 F.3d at 381 (“[C]onsultation with a lawyer confers no automatic

immunity from the legal consequences of conscious fraud.’’ (quoting *United States v. Painter*, 314 F.2d 939, 943 (4th Cir. 1963), *cert. denied*, 374 U.S. 831 (1963)); *United States v. Polytarides*, 584 F.2d 1350, 1352–53 (4th Cir. 1978) (“A crucial element in the defense of acting upon the advice of counsel is that defendant secured the advice on the lawfulness of his [p]ossible future conduct.”); *United States v. Benson*, 941 F.2d 598, 614 (7th Cir. 1991) (“[T]o negate willfulness counsel’s advice must create (or perpetuate) an honest misunderstanding of one’s legal duties. If a person is told by his attorney that a contemplated course of action is legal but subsequently discovers the advice is wrong or discovers reason to doubt the advice, he cannot hide behind counsel’s advice to escape the consequences of his violation.”), *modified*, 957 F.2d 301 (7th Cir. 1992); *United States v. Rice*, 449 F.3d 887, 896–97 (8th Cir. 2006) (“[A] defendant is not immunized from criminal prosecution merely because he consulted an attorney in connection with a particular transaction.”), *cert. denied*, 549 U.S. 1040 (2006); *United States v. Nordbrock*, 38 F.3d 440, 445–46 (9th Cir. 1994); Eric Wm. Ruschky, Pattern Jury Instrs. for Fed. Crim. Cases, D.S.C. at 631 (Aug. 15, 2016 Online Ed.) (“Good faith reliance on the advice of counsel is not a complete defense to an allegation of willful misconduct, but is merely one factor the jury may consider when determining the defendant’s state of mind.”).<sup>1</sup>

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<sup>1</sup> The United States reserves the right to argue, based on the evidence at trial, that an advice of counsel instruction is not warranted. See, e.g., *United States v. Powell*, 680 F.3d 350, 356–57 (4th Cir. 2012) (holding that defendant “failed to establish an evidentiary foundation” for advice of counsel instruction where “no evidence indicated that [defendant] disclosed facts, pertinent or otherwise, to [the company’s counsel]” and such counsel “acted only as a scrivener and did not provide legal advice when drafting the letter”), *cert. denied*, 568 U.S. 922 (2012); *United States v. Butler*, 211 F.3d 826, 833 (4th Cir. 2000) (holding that evidence of defendant’s “interactions with attorneys” did not “entitle [defendant] to an instruction regarding reliance on the advice of counsel”), *cert. denied*, 531 U.S. 1149 (2001); *United States v. Van Allen*, 524 F.3d 814, 823 (7th Cir. 2008) (holding that “no instruction was warranted” where defendant did not “produce evidence suggesting that his attorney advised him to act in any particular way” and thus defendant could not have “acted strictly in accordance with the advice of his attorney”).

## 6. Damages

### 6.1. Measure of Damages [United States]

If you find that one or more defendants violated the False Claims Act, you must award the United States such damages as will reasonably compensate it for such injury and damage as you find, from a preponderance of evidence in the case, the United States has sustained as a proximate result of the False Claims Act violations.

For a claim that results from a violation of the Anti-Kickback Statute, the measure of the United States' damages is the full amount the United States paid out for the claim.

Sources: 31 U.S.C. §§ 3729, 3731(d); Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 14 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 51, 55 (E.D. Va. Aug. 1, 2014); Jury Instructions, *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Dkt. No. 434 at 8 (S.D. Tex. Nov. 18, 2016); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386–87 (4th Cir. 2015) (“By reimbursing [defendant] for services that it was legally prohibited from paying [under the Stark Law], the government has suffered injury equivalent to the full amount of the payments.”); *United States v. Rogan*, 459 F. Supp. 2d 692, 726 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449, 453 (7th Cir. 2008) (“The government offers a subsidy (from the patients’ perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that [the provider] received on these [false claims] claims must be paid back.”); *Mortgages, Inc. v. U.S. Dist. Ct. for D. Nev.*, 934 F.2d 209, 212 (9th Cir. 1991) (“Where one or more persons have committed a fraud upon the government in violation of the FCA, each is joint and severally liable for the treble damages and statutory penalty.”); *Herman & McLean v. Huddleston*, 459 U.S. 375, 390–91 (1983).

## **6.2. Reasonable Certainty [United States]**

The United States is entitled to all damages it can prove with “reasonable certainty.” On the one hand, reasonable certainty does not require proof of damages with mathematical precision. Mere difficulty in ascertaining damages is not fatal to the United States. On the other hand, the United States is not entitled to speculative damages; that is, you should not award any amount for injury or damage, which, although possible, is wholly remote or left to conjecture. You may base your evaluation of “reasonable certainty” on opinion evidence.

Sources: *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264–66 (1946); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 51 (E.D. Va. Aug. 1, 2014).

## 7. Number of False Claims

### 7.1. Number of False Claims [United States]

If you find that one or more defendants violated the False Claims Act, you must determine the number of false or fraudulent claims.

Sources: 31 U.S.C. § 3729(a)(1); Jury Instructions, *United States ex rel. Drakeford v. Tuomey*, No. 3:05-2858-MBS, Dkt. No. 810 at 15 (D.S.C. May 8, 2013); Jury Instructions, *United States ex rel. Bunk v. Birkart Globistics GMBH & Co.*, No. 1:02-cv-1168, Dkt. No. 1312-3 at 53 (E.D. Va. Aug. 1, 2014); Jury Instructions, *United States v. AllQuest Home Mortgage Corp.*, No. 4:12-cv-2676, Dkt. No. 434 at 7 (S.D. Tex. Nov. 18, 2016); *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015).